K073559 Heraeus

510(K) Summary of safety and effectiveness of a new universal composite (project NEUN)

1 Description and intended use of the medical device

FEB - 4 2008

An improved light curing dental filling composite was developed within the scope of the project NEUN on the base of customary radical cross linking (meth)-acrylate monomers and dental glass fillers. The material is characterized by the following properties in detail:

- The material is a light curing nano hybride composite.
- The monomer matrix included is a particularly low-shrink mixture of polyether and urethane monomers preponderantly.
- A special TCD backbone monomer makes the excellent mechanical properties and the low shrinkage possible. (TCD = tricyclodecane)
- The composite material does not contain any Bis-GMA monomer making it toxicologically advantageous, as no Bisphenol-A can be released.
- The filler contained is a mixture of various particle size fractions of a customary, radiopaque dental glass.
- The composite material contains non-agglomerated nano particles cross-linking to the polymer network.
- The material has a pasty consistency and can be applied plastically into the cavity. It is hardly sticky, packable, can be moulded, cured by blue light and polished with common systems.
- Handling is comparable with customary light curing dental composite materials. For deeper cavities layering technique is recommended.

In its unpolymerized state, the composite material is plastically workable (pliable) similar to current products. Using a special initiator system reduced the sensitivity to ambient light. Cross-linking reaction is initiated with light curing devices (QTH, LED) customary in dental technology. Radical cross-linking of the (meth-) acrylate monomers occurs very fast, ensuring complete curing of a layer with a thickness of over 2 mm in an irradiation time of 20 seconds.

Thus, a highly cross-linked composite material results, fully complying with the mechanical requirements for a dental filling material in the Black classes I, II, III, IV and V according to the international standard EN ISO 4049.

2 Indication List

- Direct restorations of Black classes I-V
- Direct composite veneers
- Shape corrections of teeth
- Temporary splinting of teeth loosened by trauma or periodontal disease
- Indirect restorations (inlays, veneers)

- Restoration of primary teeth
- Core build-up
- Temporary repairs of composite and ceramics (in combination with a suitable repair-system)

3 Toxicological Evaluation

In accordance with the Medical Device Directive 93/42/EWG and national European medical device legislation, any medical device is requested to be evaluated by the legal medical device manufacturer regarding its clinical performance and safety. This includes an evaluation of biocompatibility in accordance with EN ISO 10993-1.

The biological compatibility of the prototype NEUN was verified in accordance with the international standard. The cured composite did not show a significant toxicological reaction.

The biocompatibility of NEUN in the aforementioned indication was documented in a Biological Evaluation Report and the benefit/risk-relation has to be judged as positive.

4 Physical Properties and compliance with ISO 4049

NEUN was developed with a focus to the best competitor materials known in the dental market. A comparison with approved dental materials demonstrates the properties of NEUN is far superior properties in every detail..
All important properties were proved with in-vitro tests and show similar or better results in comparison with registered and commercially available products.

The international standard EN ISO 4049 has defined basic properties for dental composite materials to ensure the clinical effectiveness. The specification of the new dental composite NEUN meets the requirements of the harmonized standard for dental restorative materials of all cavity classes (type 1, class 2, group 1).

5 Clinical Evaluation

In accordance with the Medical Device Directive 93/42/EWG and national European medical device legislation, any medical device is requested to be evaluated by the legal medical device manufacturer regarding its clinical performance and safety. This includes a clinical evaluation in accordance with MEDDEV 2.7.1., which is intended to critically evaluate the clinical benefits of the medical device in comparison to its potential risks. Therefore, any clinical evaluation is part of the compulsory risk management process according to EN ISO 14971, and critical findings must further be considered in the current risk management process of the medical device manufacturer responsible for the evaluated device.

On this background, the clinical evaluation was performed in order to comply with the current European medical device legislation, in particular with MEDDEV 2.7.1. This clinical evaluation followed the procedures outlined in the corresponding clinical evaluation plan.

NEUN is a light-curing universal composite, which is generally classified as a Class IIa medical device under the Medical Device Directive 93/42/EEC. This universal composite is intended for high-end aesthetic restorations in the anterior and posterior areas, intended for long-term application.

Considering the evaluated scientific data, clinical research and technical results for NEUN it is concluded that the product can be expected to exhibit the claimed technical performance and that potential undesirable clinical effects and risks seem well controlled and acceptable, when weighed against their benefits in dentistry. Therefore, a positive risks versus benefits ratio can be stated by the Expert for NEUN, provided

that the product is applied in accordance with its intended use as outlined in the manufacturer's information for use.

The clinical investigation report was prepared in accordance with MEDDEV 2.7.1 and followed the provisions of the corresponding clinical evaluation plan dated 05 July 2007.

6 Summarized Evaluation

The risk potential of the newly developed restorative composite NEUN was proved and evaluated with a laboratory prototype and a prototype from the production. All properties of the prototype was verified successfully. The risk potential of the newly developed material NEUN was proven with the prototype from laboratory and production.

The special composition is new, however based on a well known radical crosslink reaction of (meth)acrylate monomers. The ingredients are chemically comparable to other common dental composite materials.

The biological compatibility of the restorative material was investigated to evaluate any toxicological risk. A certified laboratory has confirmed the prototype of NEUN meets the requirements of the DIN EN ISO 10993 standard. The results was discussed in a Biological Evaluation Report and the benefit/risk-relation has to be judged as positive.

Physical Properties of NEUN was determined in comparison with the most significant competitor products. The results have shown equal or better properties of NEUN to all materials investigated. The prototype of NEUN meets the requirements of the DIN EN ISO 4049 standard of polymer based filling materials.

Based on the results of the clinical studies it is concluded that the product can be expected to exhibit the claimed technical performance and that potential undesirable clinical effects and risks seem well controlled and acceptable, when weighed against their benefits in dentistry.

The risk analysis (according to DIN EN ISO 14971) was carried out for the composition of the prototype NEUN and showed that the application of NEUN could be considered to be safe.

The prototype of NEUN meets all requirements relevant for dental restorative material in accordance with the Medical Device Directive 93/42/EWG and national European medical device legislation. Based on the actual facts NEUN could be evaluated to be effective and safe with its intended use as outlined in the manufacturer's information for use.

Wehrheim, 28. August 2007

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Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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FEB - 4 2008

Ms. Cheryl V. Zimmerman
Director, Regulatory Affairs
Heraeus Kulzer, Incorporated
4315 South Lafayette Boulevard
South Bend, Indiana 46614-2517

Re: K073554
Trade/Device Name: NEUN
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin
Regulatory Class: II
Product Code: EBF
Dated: November 29, 2007
Received: December 18, 2007

Dear Ms. Zimmerman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073554
Device Name: ___**NEUN**_____
Indications for Use:

- Direct restorations of Black classes I – V.
- Direct composite veneers
- Shape corrections of teeth
- Temporary splinting of teeth loosened by trauma or periodontal disease
- Indirect restorations (inlays, veneers)
- Restoration of primary teeth
- Core build-up
- Temporary repairs of composite and ceramics (in combination with a suitable repair system)

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073554